

*Cumulative Risk Assessment:*  
Residential & Food Exposure  
Methodology for the  
Organophosphorus Pesticides  
Technical Briefing



U.S. EPA  
Office of Pesticide Programs

November 15, 2001



# *Welcome and Introduction*

Lois Rossi, Director  
Special Review and Reregistration Division

11/19/2001 13:02



# Goals of Today's Meeting

**Lois Rossi**

Director

Special Review &  
Reregistration Division



## *Goals & Purpose of Briefing*

- Part of process the Agency has developed in conjunction with CARAT Workgroup on OP Cumulative Process
  - Update stakeholders
  - Provide explanations of methods as early as possible



## Goal

- Stakeholders understand methods & data so that they can provide effective input
- Find ways of enhancing transparency and ease of stakeholder participation



# *Cumulative Assessment Represents New “Paradigm”*

- Clearly not just a compilation of individual chemical risks
- Different way of looking at risk
  - Different questions
  - Different methods
  - Different risk management considerations



# *Developing Common Understanding of New Paradigm*

- Natural to want to know the “bottom-line”
  - What are the risk numbers?
  - What will be the regulatory outcome?
  - Will these methods be used for other groups?



# *Developing Common Understanding of New Paradigm*

- Why “bottom-line” must wait
  - Numbers will not be fully QA/QCed until preliminary risk assessment is completed
  - Need to have a common understanding of the methods/paradigm before there can be meaningful dialog on regulatory outcome
  - Application to other groups will not be known immediately
    - Depends on conclusions regarding methodology
    - Depends on specific characteristics of the other groups



# *Understanding New Methods*

- A big piece is analyzing variability
  - What are the major factors contributing to risk
    - i.e. what matters & what does not
  - Analyze information sources
  - Refine risks where necessary
  - Understanding uncertainty
  - Agency committed to doing this



## *Summary*

- Focus on methods
- Prepare for release of preliminary assessment
- Stakeholders prepared to review preliminary assessment
- Understand what is important in preliminary assessment
- Contribute to the Agency's ability to conduct appropriate refinements
- Prepare proper foundation for analyzing risk mitigation, if necessary



# *Agency & Stakeholder Cooperation*

- Due to development of many new methods for cumulative, the Agency is providing briefings on these methods & the status of the assessment before the preliminary risk assessment is issued
- Stakeholders must recognize certain elements (both small & potentially large) may change
- Therefore, we all must work together cooperatively; to use the information constructively; and for the purpose of providing useful input



# *Steps for Conducting a Cumulative Risk Assessment*

Identify Common Mechanism Group

Identify Potential Exposures

Characterize + Select Common  
Mechanism Endpoint(s)

Determine Cumulative Assessment Group

Determine Absolute & Relative Toxic Potencies of  
Chemicals & Point of Departure for Index Chemical

Develop Detailed Exposure Scenarios  
for all Routes & Durations

Establish Exposure Input Parameters

Conduct Final Cumulative Risk Assessment

Conduct Characterization of Cumulative Risk



# Overview of Today's Briefing

**Margaret Stasikow**  
Director,  
Health Effects Division



# oadmap



Probabilistic methods for cumulative



Proposed method for dietary



Residential uses



Proposed methods for residential



Summary & next steps



# *Food & Residential Team Members*

- Elizabeth Doyle
- Jeff Evans
- David Hrdy
- Carol Lang
- David Miller
- Mohsen Sahafeyan
- William O. Smith
- Bill Wooge



# **Food and Residential Exposures and the Risk Assessment Process**

**David Miller**  
HED



# oadmap



## **Probabilistic methods for cumulative**



Proposed method for food



Residential uses



Proposed methods for residential



Summary & next steps



# Introduction

- Both food and residential exposure estimates used in a probabilistic assessment for cumulative risk
  - Presentation in October covered exposures through drinking water
- Next slides detail:
  - How food risk is estimated probabilistically
  - How residential exposures would need to be estimated to be combined in a probabilistic estimate with food
  - How food and residential exposures are combined



# Outline

- Risk Equation
- Using DEEM<sup>TM</sup> software for assessments for food (alone)
- Key Concepts in Aggregation/Cumulation Methodology using DEEM<sup>TM</sup> /Calendex<sup>TM</sup>
  - Importance of calendar-based Assessment
- Illustrative step-by-step example of Probabilistic Aggregate/Cumulative Assessment for Food and Residential Exposures



## *Risk Equation*

- Risk is the probability that a substance will produce harm under specified conditions
- Risk = Exposure X Hazard
  - Hazard part derived from toxicological studies
  - Exposure part derived from
    - FOOD: residues and consumption
    - RESIDENTIAL: residues and contact



## *Exposure From Food*

- We use DEEM™ (Dietary Exposure Evaluation Model) software to estimate exposures from food
  - Exposure = Consumption X Residue
  - DEEM™ produces an estimate of the distribution of exposures through food
    - Uses probabilistic (Monte-Carlo) techniques



# *EEM<sup>TM</sup> Software*

- Uses data on food consumption and data on pesticide concentration to estimate exposures from food
  - Food Consumption
    - USDA's Continuing Survey of Food Intakes by Individuals (CSFII)
    - Survey reports daily consumption of food for 40,000+ person-days of consumption
    - 1994-96/1998 data available
  - Pesticide Residues
    - Market Basket Data
    - USDA PDP data
    - FDA Monitoring data



# *Key Concepts in Cumulative Assessment*

## *Appropriate Matching and Combining*

- Objective: to appropriately match and subsequently combine estimates of pesticide exposures through food with estimates of pesticide exposures through residential uses

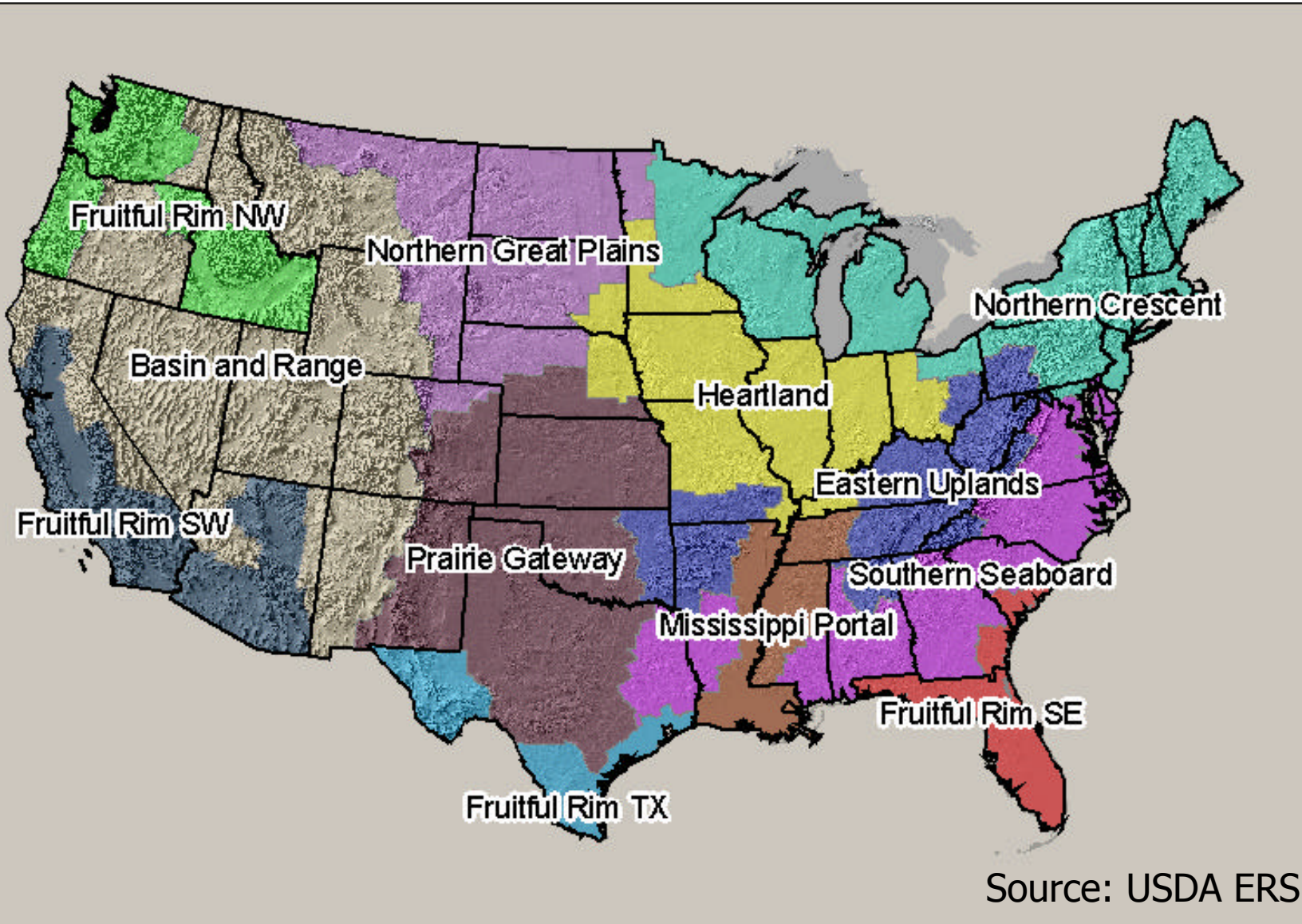


# *Key Concepts in Cumulative Assessment*

## *Appropriate Matching and Combining*

- Matching and combining must appropriately consider temporal and spatial factors associated with exposure
  - Temporal Factors
    - The time of year that pesticide exposures occur
      - E.g., springtime
    - Pesticide exposures on one day can be related to pesticide exposures on previous day
      - E.g. day-to-day relationships
  - Spatial Factors
    - Region of Country in which pesticide exposures occur
      - E.g., South vs. North

# *Regional Framework*





# ***DEEM<sup>TM</sup>/Calendex<sup>TM</sup> Cumulative Assessment***

DEEM<sup>TM</sup>/Calendex<sup>TM</sup> provides a probabilistic assessment in which appropriate matching occurs

- Incorporates concept of a Calendar to evaluate aggregate exposures
- Looks at each individual day of the year
  - Allows appropriate “temporal matching” of exposures through food, drinking water, and residential pathways.
  - Temporal aspect of exposure through residential uses important for OP’s due to expected seasonal use-patterns



## *EEM<sup>TM</sup>/Calendex Cumulative Assessment*

- What would happen if we didn't use calendar-based approach?
- For example:
  - Fall dermal exposure through lawn-use could be (incorrectly) combined with dermal exposure through spring flea treatment on pets
  - Oral hand-to-mouth exposure from spring lawn application on one day could be (incorrectly) combined with drinking water concentration characteristic of the winter season



## *Key Concepts in Cumulative Assessment Appropriate Matching and Combining*

- In summary, must track potentially exposed persons on a daily basis in a way that preserves all appropriate linkages in a way that considers time, region, and age groups



# *Quantitative Exposure Assessment: Calendex<sup>TM</sup>/DEEM<sup>TM</sup> & Region-specific Analysis*

- For each assessment region:
  - Maintain temporal & spatial characteristics
  - Use DEEM<sup>TM</sup> software to estimate exposure from food
  - Use Calendex<sup>TM</sup> software to aggregate/cumulate exposure from food and residential exposures and drinking water



## *Age Groups*

- Assessment performed for the following age groups:
  - Children 1-2 years old
  - Children 3-5 years old
  - Adults 20-49 years old
  - Adults 50+



## *Illustrative Example of Calendex™ Analysis*

- 1-day exposure is presented as an example
- Analysis serves as “building block” for any number of days analysis
- Only food & residential included in this example



# *Illustrative Example of Calendex™ Analysis*

- Hypothetical Consumption Profile for CSFII Individual #1
  - 12 kg child
  - Consumed:
    - 260 g food #1
    - 320 g food #2
    - 250 g food #3
- Period of Interest: January 1 through December 31
- Specific to Region of Interest



## *Illustrative Example of Calendex™ Analysis*

- STEP 1: Calculate Exposure from Food for Individual # on January 1
  - Food Exposure(from DEEM™): =  $2.89 \times 10^{-5}$  mg/kg bw/day
- STEP 2: Select Residential Treatments for Individual # on January 1
  - Specific to region & time and demographics of individual
  - Assigned probabilistically
    - Were pesticides applied in/around home?
    - If so, which treatments?
      - And how much, how often, during what time frame, with what frequency, and by whom?



## *Illustrative Example of Calendex™ Analysis*

- STEP 3: Calculate Exposure from any assigned new residential uses for January 1
- STEP 4: Determine if Exposure is “Active” from any previously assigned use/application
  - by oral (hand to mouth) exposure to children (2 days earlier)
- $$\text{Exposure} = \frac{\{\text{ISR} - 2\text{DAT} \times \text{Surf Area}_{\text{finger}} \times \text{No. events/hr} \times \text{No. hours} \times \text{Saliva Removal efficiency}\}}{\text{body weight}}$$
- $$= 1.33 \times 10^{-5} \text{ mg/kg BW/day}$$
- STEP 5: Aggregate exposures for Day #1 from Food and (any active) Residential Uses
- $$= 2.89 \times 10^{-5} \text{ mg/kg BW/day} + 1.33 \times 10^{-5} \text{ mg/kg BW/day}$$



## *Illustrative Example of Calendex™ Analysis*

- STEP 6 : Repeat Steps 1-5 many additional times for this individual, randomly selecting a series of treatment scenarios for that year, determining if any are applicable or otherwise “active” for Day #1 for that individual, and aggregating (summing) selected food and residential exposures
- STEP 7: Continue steps 1-6 with Individual #2 through Individual # ~20,000
  - Result is a collection (or distribution) of aggregate exposures for January 1 for the relevant region
- STEP 8: Repeat steps 1-7 for January 2
  - Result is a collection (or distribution) of aggregate exposures for January 2 for the relevant region

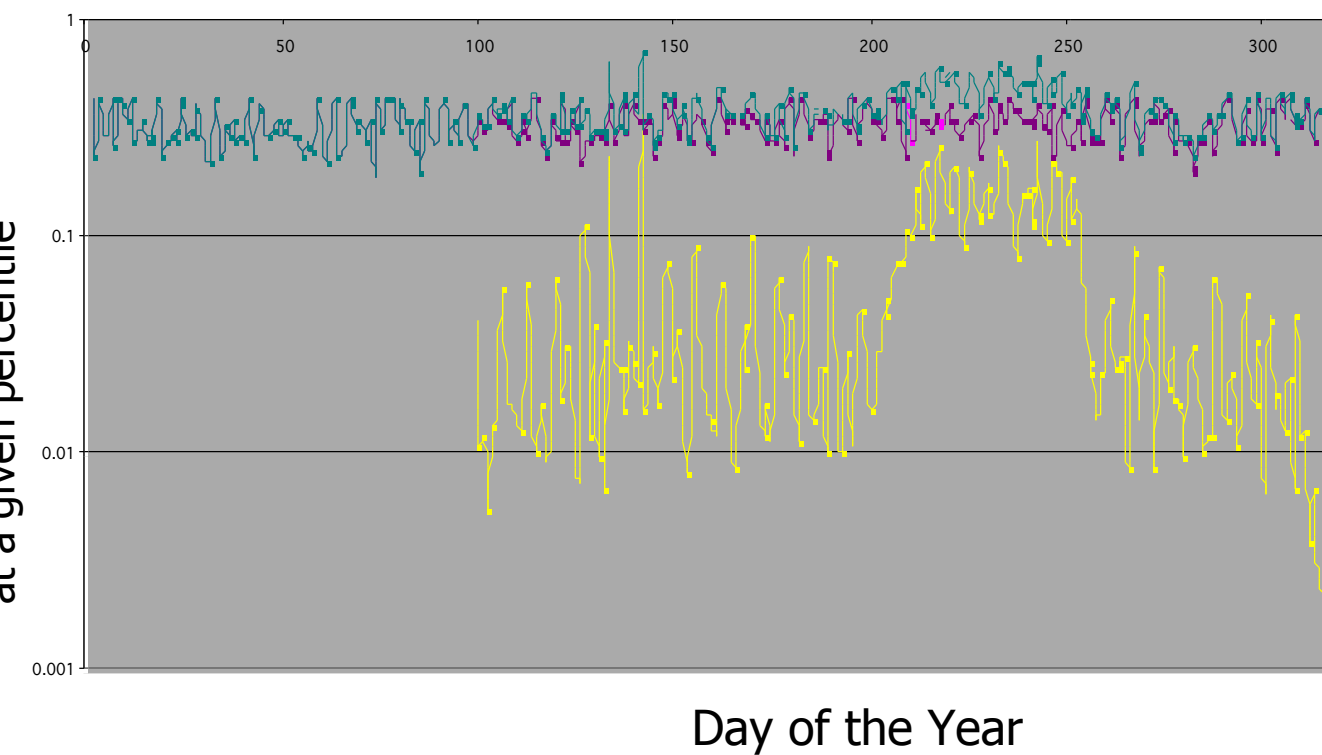


## *Illustrative Example of Calendex™ analysis*

- STEP 9: Repeat steps 1-8 for January 3 through December 31
  - Result is a collection (or distribution) of aggregate exposures (food and residential combined) for each day of the year for the relevant region
  - These exposures can be plotted as a “time-line” or profile of daily exposures for any given percentile in the distribution



# *Example of Calendex<sup>TM</sup> Analysis (time based exposure profile)*





## *Summary*

- Food and residential exposures and water will be considered probabilistically in the cumulative assessment
  - Reflects realistic pesticide use based on pest pressures, weather, activity patterns, etc.
  - Temporal and spatial characteristics will be preserved and maintained to produce realistic assessments



## *Summary*

- Result of Assessment will be a time based exposure profile of exposures at any selected percentile
  - Total Exposure and its food, residential (and water) components
  - Single-day assessments will serve as “building block”



# CUMULATIVE DIETARY EXPOSURE FROM USES OF ORGANOPHOSPHORUS PESTICIDES

**William O. Smith**  
Health Effects Division



## *urpose*

- Describe methods used and assumptions involved in cumulative dietary exposure assessment for organophosphorus pesticides using an RPF approach and the DEEM™ model



## *Outline of Presentation*

- **Scope of food exposure assessment**
- Approach to combining residues
- Calculation of residue inputs
- Discussion of assumptions in assessment



# *Scope of Food Assessment*

- Sources of Residue Data
- OPs included
- Foods included



## *Scope of Food Assessment Sources of Residue Data*

- USDA Pesticide Data Program (PDP)  
<http://www.ams.usda.gov/science/pdp>
- FDA Center for Food Safety & Applied Nutrition  
<http://www.cfsan.fda.gov/~lrd/pestadd.html>  
Pesticide Residue Monitoring Program  
Total Diet Study (TDS)



# ***USDA Pesticide Data Program***

- Designed to provide data on dietary exposure
  - Started in 1991
  - Samples foods highly consumed by children
  - Reflect foods typically available throughout year
  - Foods collected near point of consumption
  - Food washed and inedible portions removed before analysis



## *DA Monitoring Data*

- Designed to enforce EPA tolerances in imported foods and in domestic foods shipped in interstate commerce
- Domestic samples are collected as close as possible to the point of production in the distribution system
- Import samples are collected at the point of entry into U.S. commerce
- Emphasis is on the raw agricultural product, which is analyzed as the unwashed, whole (unpeeled), raw commodity. Processed foods are also included



# *DA Total Diet Study*

- Provided data on dietary intake of food contaminants for almost 40 years
- Since 1991 26 market baskets collected
- Each MB includes ~ 260 foods collected in grocery stores
- Analyses performed on foods prepared for consumption
  - Highly sensitive analyses
  - Limited number of samples



## *Ps Included in Current Food Assessment*

- Acephate, azinphos methyl, chlorpyrifos, chlorpyrifos-methyl, disulfoton, diazinon, dichlorvos, dimethoate, ethoprop, fenamiphos, malathion, methidathion, methamidophos, mevinphos, oxydemeton-methyl, methyl parathion, phorate, phosolone, phosmet, pirimiphos methyl, terbufos, & tribufos



## *OPs Not Included in Current Assessment*

- OP uses that have been voluntarily cancelled
- OPs that only have public health uses
- OPs with no detectable residues in monitoring



## ***DP Foods Included***

**Apples  
Apple Juice  
Bananas  
Broccoli  
Celery  
Cantaloupe  
Carrots  
Sweet Corn  
Cucumbers  
Corn Syrup  
Cherries  
Ice**

**Green Beans  
Grapes  
Grape Juice  
Lettuce  
Milk  
Oats  
Oranges  
Orange Juice  
Peaches  
Pears  
Nectarines  
Pineapple**

**Potatoes  
Bell Peppers  
Strawberries  
Sweet Potatoes  
Soybean  
Spinach  
Sweet Peas  
Tomatoes  
Wheat  
Winter Squash  
Poultry  
Peanut Butter**



# *DP Food Types*

## Fruits and Vegetables

Fresh

Frozen

Canned

## Fruit Juices

Ready-to-Drink

Frozen

Concentrate

## Grains

Whole

## Milk

Whole

## Poultry

Fat

Liver

Muscle



## *DP Food Coverage*

- 44 Food Types Representing 86% of the Diet of Children 3-5
  - (CSFII 94-96,98)



## *oods Based on Translated PDP Data*

Eggplant	Rutabagas
Pepper(other than green)	Turnips
Citrus (other than orange)	Various leafy greens
Apricots	Brussels sprouts
Plums/Prunes	Cabbage
Rye	Cauliflower
Beets-garden	Melons(other than cantaloupe)
Horseradish	Pumpkins
Parsnips	Squash-summer
Radishes	

Represent 1.3% of Diet of Children 3-5 (CSFII)



## *oods Based on FDA Monitoring Data*

- Eggs
  - Assume negligible based on FDA monitoring data
- Seafood
  - Assume negligible based on FDA monitoring data
- Meat from Beef, Pork, Sheep & Goats
  - Used maximum residues found in FDA/TDS

Represent 6.3% of Diet of Children 3-5 (CSFII)



## *oods Assumed Negligible*

- Sugarcane, Sugar Beet & Maple
  - Molasses, syrup & sugar
- Assume negligible residues
  - Highly processed/refined
  - No residues in sugar or pancake syrup analyzed by FDA/TDS
  - No residues in corn syrup analyzed by PDP

Represent 3.1% of Diet of Children 3-5 (CSFII)



## *Total Food Forms Included in Assessment*

- DEEM: 547 foods based on CSFII
- OP food assessment: 258 foods
  - 154 expanded from 44 PDP commodities
  - 54 by translation of PDP data
  - 29 meats from TDS data
  - 12 fish and eggs from FDA
  - 9 sugar, molasses, & syrup by inference



## *Food Forms Not Included in Current Assessment*

- Highly processed foods
- Infrequent detectable residues
- Residues detected negligible



## *The Proportion of the Diet of Children (3-5) Covered in the Cumulative assessment*

<u>Source of Residue Estimate</u>	<u>% of Diet</u>
PDP	85.7
Translation of PDP	1.3
FDA	6.3
Assumed negligible	3.1
Not included	3.6



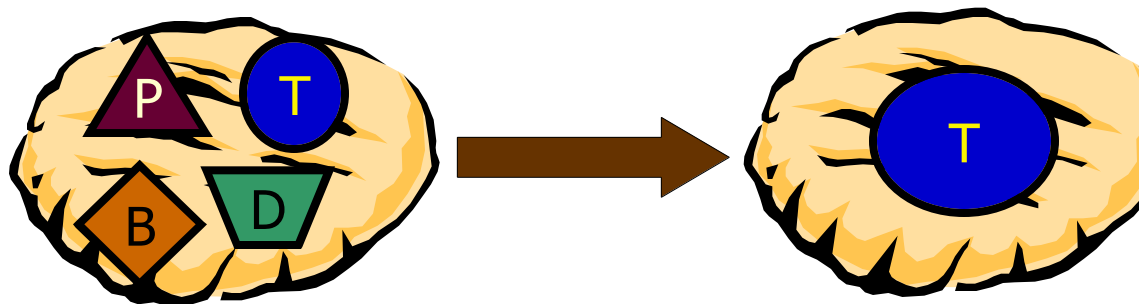
## *Outline of Presentation*

- Scope of food exposure assessment
- **Approach to combining residues**
- Calculation of residue inputs
- Discussion of assumptions in assessment



# *PF Approach*

Converts chemical specific residues (B,D,P,T) on a food sample to a common residue (T)



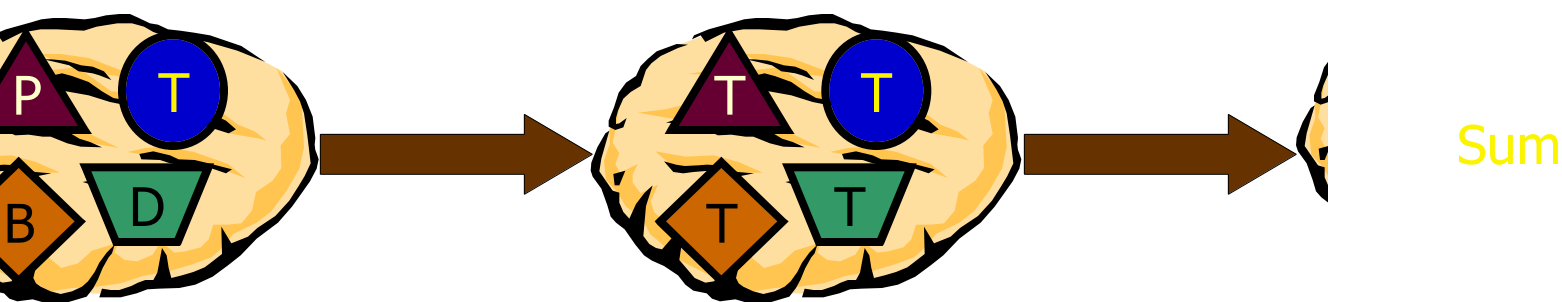


# Two Steps Needed to Derive Cumulative Residue<sub>IE</sub>

$$1. \text{Residue}_{IE} = \text{Residue} \times PF \times RPF$$

*PF=processing factor*

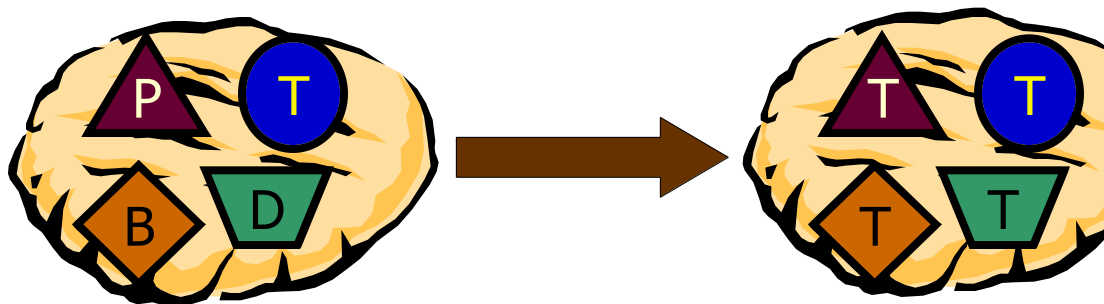
$$2. \text{Cumulative Residue}_{IE} = \text{Residue}_{IE} (\text{per PDP sample})$$





## Step #1: Index Equivalent Residue ( $Residue_{IE}$ )

$$Residue_{IE} = \text{Residue} \times PF \times RPF$$





## *Calculation Parameters for Residue<sub>IE</sub>*

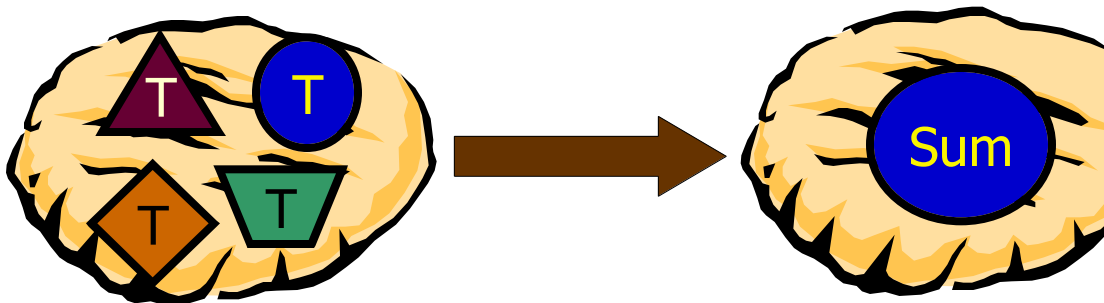
$$\text{Residue}_{IE} = \text{Residue} \times \text{PF} \times \text{RPF}$$

- **Residue:** PDP residue data by sample
- **PF:** Processing factors from single chemical assessments.
- **RPF:** Relative Potency Measure.



## Step 2: Cumulative Residue

$$\text{Cumulative Residue}_{\text{IE}} = \text{Residue}_{\text{IE}} \text{ (per PDP sample)}$$



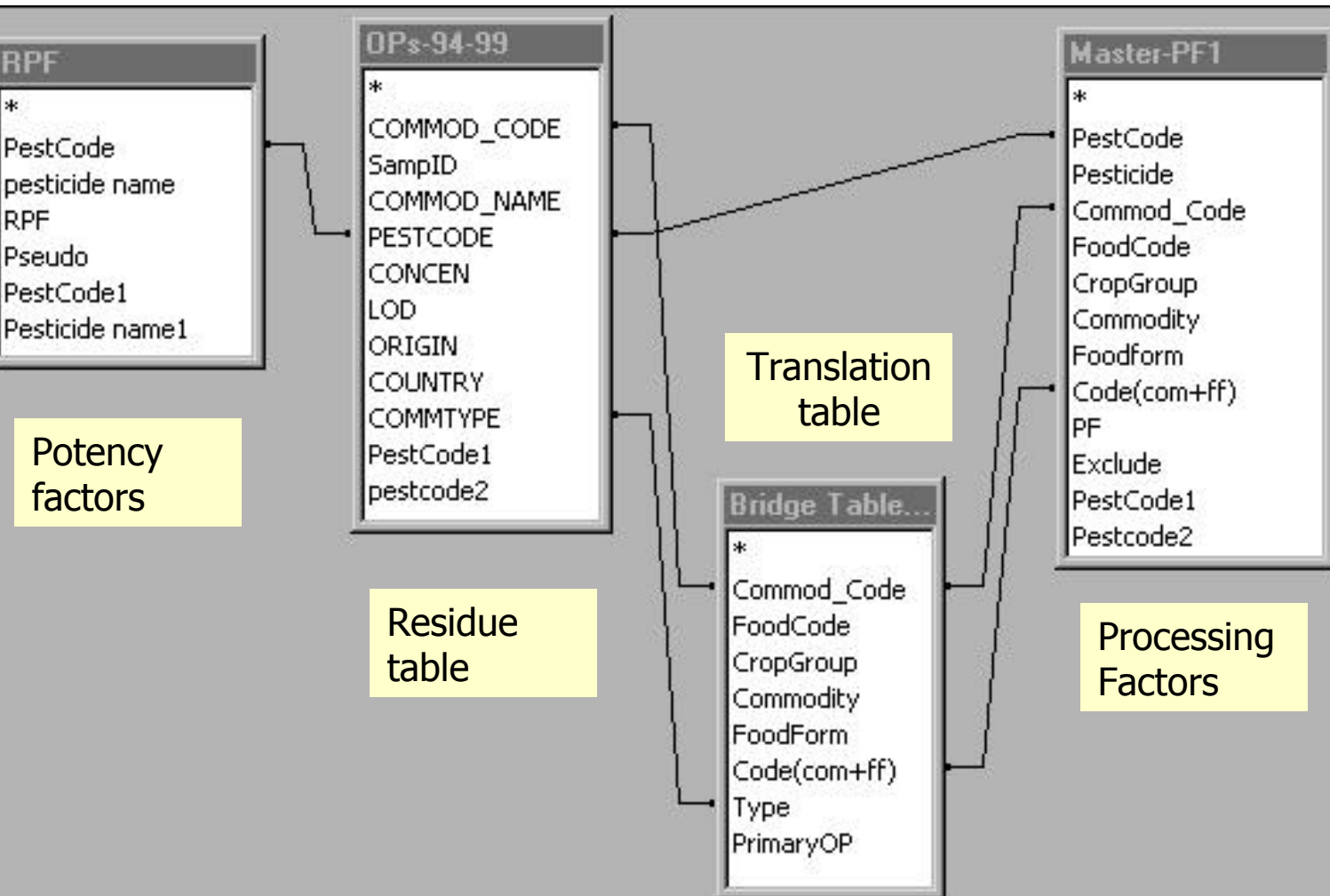


## *Outline of Presentation*

- Scope of food exposure assessment
- Approach to combining residues
- **Calculation of residue inputs**
- Discussion of assumptions in assessment



# Data Tables (screen print)





# DP Data Table (screen print)

Microsoft Access - [DPs-94-99 - Table]

File Edit View Insert Format Records Tools Window Help

SampleID	COMMOD	COMMTYP	COMMOD_NAME	CONCEN	LOD	ORIGIN	COUNTR	PestCod
A9401240053GR	GR	FR	Grapes	0	0.02	2	275	M
A9401240053GR	GR	FR	Grapes	0	0.002	2	275	W
A9401240053GR	GR	FR	Grapes	0	0.003	2	275	A
A9401240053GR	GR	FR	Grapes	0	0.02	2	275	G
A9401240053GR	GR	FR	Grapes	0.005	0.003	2	275	RA
A9401240053GR	GR	FR	Grapes	0	0.003	2	275	I
A9401240053GR	GR	FR	Grapes	0.005	0.003	2	275	R
A9401240053GR	GR	FR	Grapes	0	0.003	2	275	S
A9401240053GR	GR	FR	Grapes	0	0.003	2	275	U
A9401240053GR	GR	FR	Grapes	0	0.003	2	275	P
A9401240053GR	GR	FR	Grapes	0	0.02	2	275	ZA
A9401240053GR	GR	FR	Grapes	0	0.01	2	275	V
A9401240053GR	GR	FR	Grapes	0	0.02	2	275	X
A9401240053GR	GR	FR	Grapes	0	0.003	2	275	J
A9401240053GR	GR	FR	Grapes	0	0.003	2	275	B
A9401240053GR	GR	FR	Grapes	0	0.003	2	275	T
A9401240053GR	GR	FR	Grapes	0	0.003	2	275	C
A9401240053GR	GR	FR	Grapes	0	0.003	2	275	N
A9401240053GR	GR	FR	Grapes	0	0.01	2	275	IA
A9401240053GR	GR	FR	Grapes	0	0.006	2	275	F
A9401240053GR	GR	FR	Grapes	0	0.003	2	275	O
						0		

Records: 24 of 21 (Filtered)

Year+Month+Day+Site+Commodity

FLTR: NUM

Microsoft Access - Microsoft Excel - Microsoft PowerPoint



# Processing Factor Table

Microsoft Access - [Master-PF1 : Table]

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	Comm	CropGroup	Commodity	Foodform	Code	PF	PestCode	Exclud
	GR	O	Grapes	Uncooked	1311	1	P	<input type="checkbox"/>
	GR	O	Grapes	Uncooked	1311	1	T	<input type="checkbox"/>
	GR	O	Grapes	Uncooked	1311	1	M	<input type="checkbox"/>
	GR	O	Grapes	Uncooked	1311	1	J	<input type="checkbox"/>
	GR	O	Grapes	Uncooked	1311	1	S	<input type="checkbox"/>
	GR	O	Grapes	Uncooked	1311	1	W	<input type="checkbox"/>
	GR	O	Grapes	Uncooked	1311	1	V	<input type="checkbox"/>
	GR	O	Grapes	Uncooked	1311	1	A	<input type="checkbox"/>
	GR	O	Grapes	Uncooked	1311	1	R	<input type="checkbox"/>
	GR	O	Grapes	Uncooked	1311	1	RA	<input type="checkbox"/>
	GR	O	Grapes	Uncooked	1311	1	C	<input type="checkbox"/>
	GR	O	Grapes	Uncooked	1311	1	B	<input type="checkbox"/>
	GR	O	Grapes	Uncooked	1311	1	FB	<input type="checkbox"/>



## *Relative Potency Factors Table*

- Identifies Relative Potency Factors for all Chemicals in the assessment



# Translation Table

- Links PDP foods and types to DEEM food form codes
  - Correlates PDP commodities with CSFII
  - Translations of data can be set in this table

Commod_Code	FoodCode	CropGroup	Commodity	FoodForm	Code(com+ff)	Type	PrimaryOP
GR	13	0	Grapes	Uncooked	1311	FR	R
GR	13	0	Grapes	Cooked: NFS	1312	FR	R
GR	13	0	Grapes	Canned: NFS	1331	FR	R



**Cumulative ResidueIE = Sum ResidueIE (per PDP sample)**

**Microsoft Access - [Query3-for-Picture : Select Query]**

File Edit View Insert Format Records Tools Window Help



SampID	Chemical	COMMOD	FoodForm	CONCEN	PF	RPF	Residue(IE
L9602140006GR	R	Grapes	Uncooked	0.55	1	0.07797	0.04288
L9602140006GR	P	Grapes	Uncooked	0.44	1	0.09714	0.04274
L9602140006GR	W	Grapes	Uncooked	0	1	0.61022	0.00000
L9602140006GR	V	Grapes	Uncooked	0	1	0.01661	0.00000
L9602140006GR	T	Grapes	Uncooked	0	1	1.00000	0.00000
L9602140006GR	S	Grapes	Uncooked	0	1	0.69178	0.00000
L9602140006GR	R	Grapes	Uncooked	0	1	0.07797	0.00000
L9602140006GR	M	Grapes	Uncooked	0	1	0.09689	0.00000
L9602140006GR	J	Grapes	Uncooked	0	1	0.30132	0.00000
L9602140006GR	C	Grapes	Uncooked	0	1	0.01090	0.00000
L9602140006GR	B	Grapes	Uncooked	0	1	0.01886	0.00000
L9602140006GR	A	Grapes	Uncooked	0	1	0.46537	0.00000

**L9602140006GR ..... 0.08562**



# Cumulative Residue Distribution

<b>SampID Lookup</b>		Food	Grapes
		Form	Uncooked
		CSFII Code	1311
		Number of Samples	1884
<b>Save rdf as Txt in C:\temp</b>	Current Selection	FL9602140006GR	
<b>Send rdf to Excel</b>	ListIndex	6	
<b>Return to Form1</b>			

Sample ID	Cumulative Residue
CA9402140146GR	0.167282768428326
CA9405110140GR	0.163661572813988
MI9404180005GR	0.153586479738355
CO9411080003GR	0.144635109901428
NC9401240004GR	0.125257762625813
OH9507250104GR	0.114611417725682
FL9602140006GR	8.56233570724726E-02
OH9401110208GR	7.83440178632736E-02
NY9603060011GR	0.075533320762217
MI9411080048GR	7.53307864069939E-02
MI9604150008GR	6.93905862420797E-02
TX9601310402GR	5.62551636397839E-02
CO9506050011GR	5.47088390439749E-02
FL9603130018GR	5.13816663622856E-02
NC9505080014GR	4.86797152459621E-02
CA9504170151GR	4.83395095169544E-02
WA9411080002GR	4.82117033004761E-02
CA9406210130GR	4.82117033004761E-02



# *Residue Inputs for Food Assessment*

- 220 Residue Distribution Files (RDFs) for different food forms
- 201 point estimates for blended foods or other data sources

```
1311-grapes-uncooked-10-12.rdf - Notepad
File Edit Search Help
1311 = grapes-uncooked
#samples = 1884
#detects = 457
#zeros = 1427
0.167282773
0.163661569
0.15358648
0.144635106
0.12525776
0.114611415
0.085623357
0.078344016
0.07553332
0.075330785
0.069390584
0.056255164
0.054708838
0.051381666
0.048679714
0.048339508
0.048211702
0.048211702
0.046491737
```



# *Cumulative Dietary Risk*

- Exposure = Residue X Consumption



Cumulative Residue<sub>IE</sub>  
for OPs



CSFII 94-98



# *Consumption*

- USDA Continuing Survey of Food Intakes by Individuals
  - CSFII, 1994-1998



## ***SFII 1994-96/1998***

- Intakes of individuals residing in U.S.
- 20,607 individual participants interviewed over two discontinuous days
- 1998 Supplemental Children's Survey
  - 5,559 additional children
  - Birth through 9 years old
  - Integrated into 1994-96 CSFII



## ***CSFII 1994-96/1998***

- The 1994-96/1998 CSFII significantly increases the number of children in the survey compared to the 1989-91 survey data currently being used by OPP

*Comparison of Number of 1-day and Complete  
Intakes, by Children's Age Group  
1994-96/1998 vs. 1989-91 CSFII*

Age Group	1994-96/1998 CSFII		1989-91 CSFII	
	No. Individuals	No. Person- days	No. Individuals	
1	1408	~	197	
2	2179	4114	574	
5	4579	8464	806	
11	2000	3706	1476	



# *Consumption*

- USDA Continuing Survey of Food Intake by Individuals (CSFII) database
  - OP cumulative risk assessment uses 1994-96/1998 data with new (USDA/EPA) recipes
  - Respondents in the CSFII survey report what they ate in the form the food was eaten



# *Food to RAC Mapping/Translation*

- Food consumption reported on an “as-eaten” basis
  - 200 g pizza
  - 100 g “Toasted Oat cereal”
- “Linked” or translated to the raw agricultural commodities for which we have residue data
  - Linking is done with USDA/USEPA recipes
  - Will be publicly available



# *Consumption*

- Assessment based on survey information on the following age groups:
  - Children 1-2 years old
  - Children 3-5 years old
  - Adults 20-49 years old
  - Adults 50+ years old



# Model

- Dietary Exposure Evaluation Model – DEEM-FCID™
- Probabilistic (Monte-Carlo) procedure
- Input:
  - Distributions for consumption
  - Distributions or point estimates for residue concentrations
- Output:
  - Distribution of one-day dietary exposures
  - Distribution of associated risks, i.e., MOEs



## *Outline of Presentation*

- Scope of food exposure assessment
- Approach to combining residues
- Calculation of residue inputs
- **Discussion of choices & assumptions in assessment**



## *Choices & Assumptions*

- The assessment includes only chemical/crop combinations currently registered in U.S. or with import tolerances
  - Canceled & phased-out uses from single chemicals assessments are excluded
  - Violative residues are not included in assessment



## *Choices & Assumptions*

- PDP samples were assumed to reflect residues as consumed
  - Used composite samples
  - Did not “decomposite” residues
  - PDP special surveys on single-servings of apples, pears, & peaches support use of composites



## *Choices & Assumptions*

- PDP samples were assumed to reflect residues as consumed
  - Samples generally taken from wholesale distribution centers
  - Foods washed, peeled, etc. similar to preparation for consumption
  - Foods were not cooked



## *Choices & Assumptions*

- Residue data in PDP are assumed to represent the potential for co-occurrence of OPs in single-day diets
  - Different foods consumed in one day may each contain OP residues
  - A single food may contain residues of more than one OP



## *Choices & Assumptions*

- It was assumed that all OPs of concern were accounted for on each PDP sample
  - If an OP was not detected on a sample then it was assumed = zero
  - i.e., percent crop treated implicit in detection rate, subject to sensitivity of analytical method



## *Choices & Assumptions*

- Higher percentiles of exposure not expected to be significantly affected by assumption of  $ND=0$ , given that cumulative residues significantly higher than LOD are abundant in the data
- This was demonstrated in the case study 12/99



## *Choices & Assumptions*

- PDP residue data may be translated to foods not analyzed if similar agricultural practices are in effect
  - OPP/HED SOP 99.3



## *Choices & Assumptions*

- PDP residue data may be translated to foods not analyzed if similar agricultural practices are in effect
  - 54 foods in this assessment were included by translation of PDP data
  - Translated to foods that are not major consumption items (~1% of child's diet)



## *Choices & Assumptions*

- The food exposure component of the cumulative assessment is considered to be identical throughout the year and across regions, i.e., one national assessment will be performed.
- The national food estimate will be combined with 13 regional water assessments to provide for 13 regional dietary assessments.



## *Future Work*

- Impact of OP Market Basket Study



# *P Market Basket Study*

- Currently being reviewed
- 13 foods analyzed for 29 OP analytes
  - Single serving samples
  - Samples from grocery stores
  - Very low limits of detection
  - Good coverage of metabolites
- Preliminary analysis indicates similar dietary exposure estimate whether using PDP or Market Basket Survey.



# *POP Market Basket Study*

- Apples
- Broccoli
- Cherries
- Cucumbers
- Green beans
- Grapes
- Peaches
- Sweet corn
- Lettuce
- Orange
- Potatoes
- Strawberries
- Tomatoes



## *uture Work*

- Analysis of exposure contributors
  - Pesticides
  - Foods
- Sensitivity analysis of omitted foods
- Incorporation of regulatory actions
- Incorporation of information from public comments



# *Current Status of OP Residential Uses*

**Deanna Scher**

Special Review &  
Reregistration Division



## *7 OPs with Uses in Residential and/or Public Areas Prior to Reassessment*

- 6 OPs are now excluded entirely from the residential cumulative assessment
  - Diazinon
  - Dimethoate
  - Ethoprop
  - Fenitrothion
  - Phosmet
  - Propetamphos
- 11 OPs with remaining residential uses



## *Residential OP Usage: Reduction of use inside the home*

- Initially 9 OPs with indoor uses
  - Now only DDVP
- Initially 6 OPs with pet uses
  - Now only tetrachlorvinphos and DDVP
- Indoor use of chlorpyrifos, fenitrothion, and trichlorfon
  - Pre-packaged child-resistant bait stations (negligible exposure)



## *Reduction in Overall OP Usage*

- Diazinon + Chlorpyrifos
  - Residential use reduction of >20 million lbs. ai



# *Protecting Public Health Uses*

- Public health uses have been retained where individual assessments indicate that these applications do not pose risks of concern and provide important public health benefits
  - Chlorpyrifos fire ant mound treatment
  - Chlorpyrifos mosquito control
  - Fenthion mosquito control
  - Naled mosquito and black fly control
  - Phosmet fire ant mound treatment



## *Four OPs with Residential/Public Uses Have Individual Risk Mitigation*

- Acephate, bensulide, chlorpyrifos, trichlorfon
- All remaining uses show risks below EPA's level of concern on an individual basis
- The cumulative assessment reflects the most up-to-date residential use picture



# *Four OPs with Residential/Public Uses Are Still Under Review*

- Dichlorvos
- Fenamiphos
- Malathion
- Tetrachlorvinphos
- Any residential mitigation actions taken on these 4 OPs will be incorporated into the revised cumulative assessment



# **Residential Exposure Assessment Process**

**Jeff Evans**

Health Effects Division



# oadmap



Probabilistic methods for cumulative



Proposed method for dietary



Residential uses



**Proposed methods for residential**



Summary & next steps



## *urpose*

- Use of a calendar based model to address the temporal use of residential OP's
  - Calendex™
- Use of distributions of data and exposure elements
- Use of survey data and other pesticide use information
- Approach is similar to the OP case study presented to SAP (12/7-8/00)



## *Expression of Residential Risk*

$$\text{MOE} = \frac{\text{POD (mg/kg/day)}}{\text{Exposure (mg/kg/day)}}$$

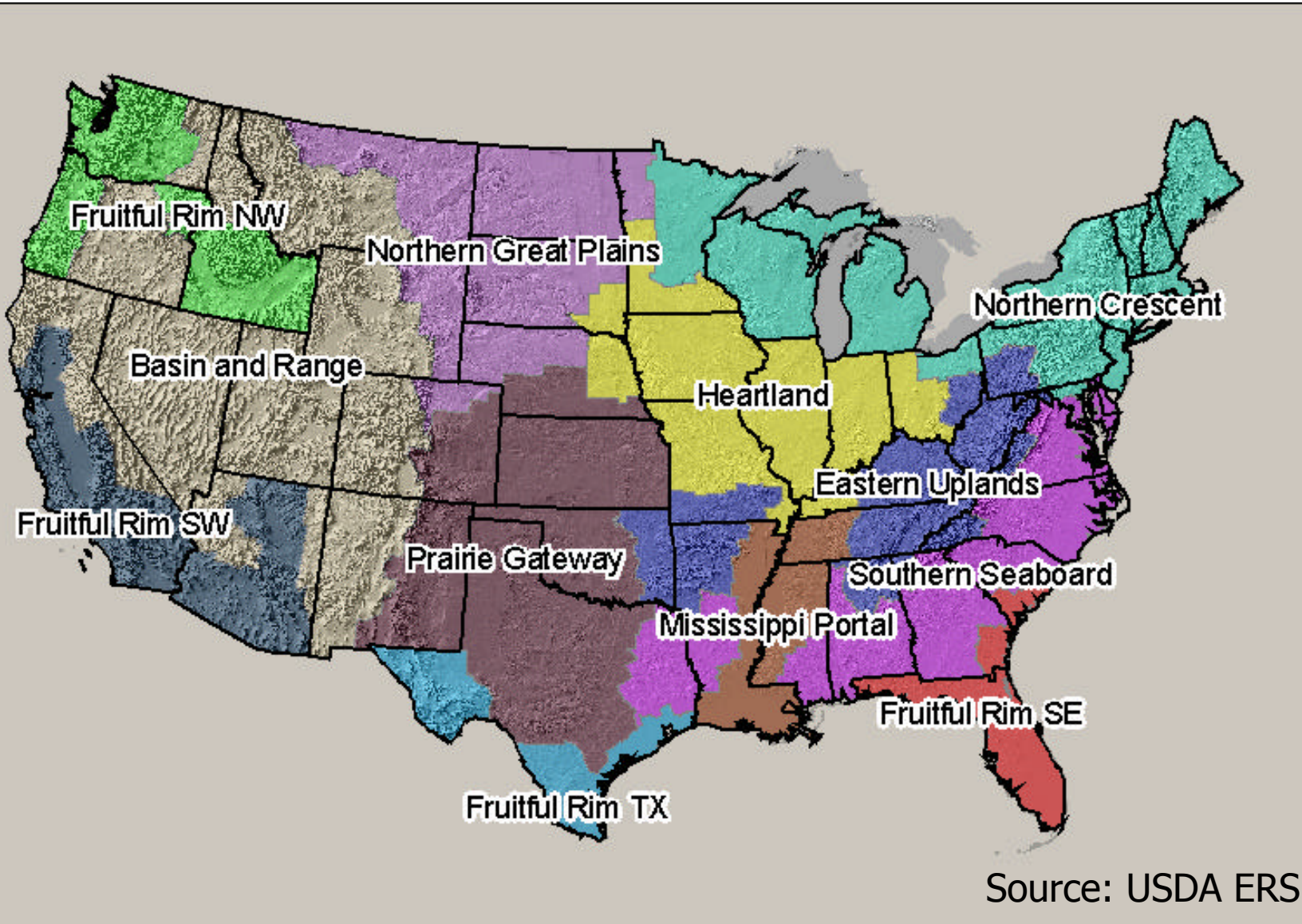
- Routes considered, as appropriate
  - Oral, Dermal, Inhalation



## *cope*

- Assessments conducted for 12 distinct geographical regions, reflecting climate & pest pressure differences
  - One region split into two residential assessments
- Includes remaining residential OPs that have significant exposure and exposure data
- Pet products not quantified
  - Only screening level SOPs available at this time

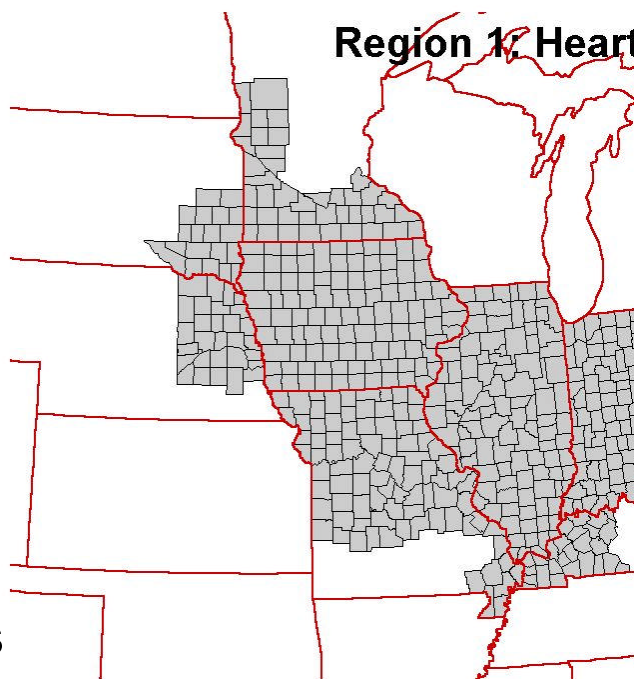
# *Regional Framework*





# Region 1 - Heartland

- Lawn use – DDVP, Malathion, Trichlorfon
- Golf course - Bensulide, Trichlorfon
- Ornamental gardens - Acephate, Disulfoton, Malathion
- Home gardens, etc. - Malathion
- Indoor - DDVP (pest strips and crack and crevice sprays)





## *Region 2 - Northern Crescent*

Lawn - DDVP, Malathion,  
Trichlorfon

Golf course - Bensulide,  
Trichlorfon

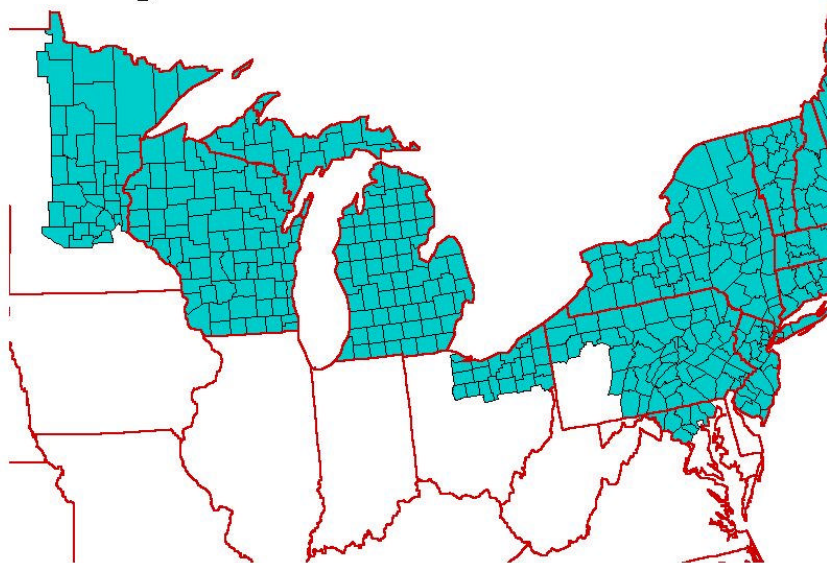
Ornamental gardens - Acephate,  
Disulfoton, Malathion

Home gardens - Malathion

Indoor - DDVP (pest strips and  
crack and crevice treatments)

Public Health - Malathion, Naled

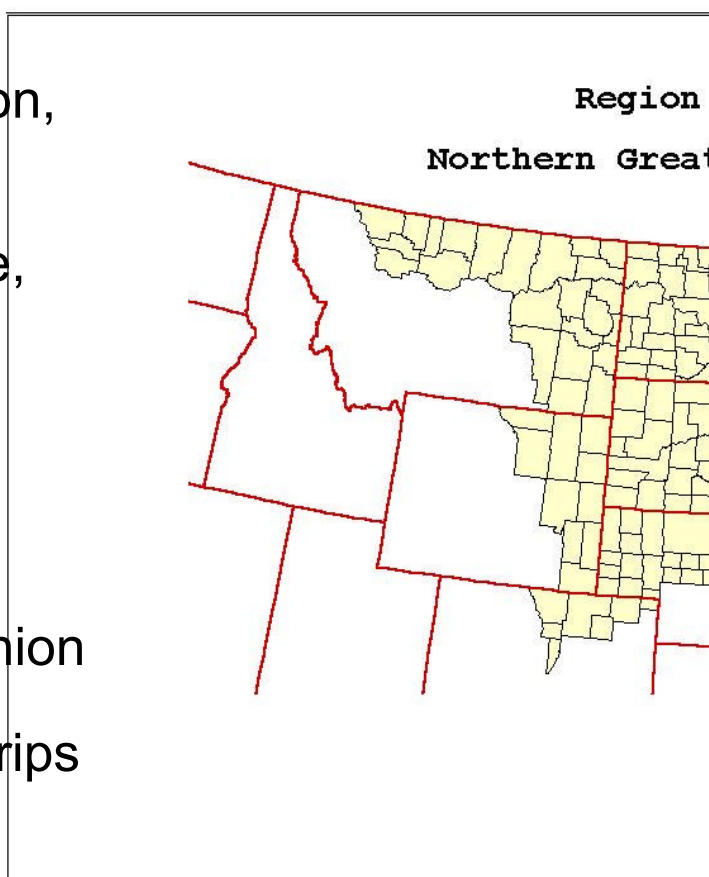
Region 2 : Northern Crescent





## Region 3 – Northern Great Plains

- Lawn - DDVP, Malathion, Trichlorfon
- Golf course - Bensulide, Trichlorfon
- Ornamental gardens - Acephate, Disulfoton, Malathion
- Home gardens - Malathion
- Indoor - DDVP (pest strips and crack and crevice treatments)

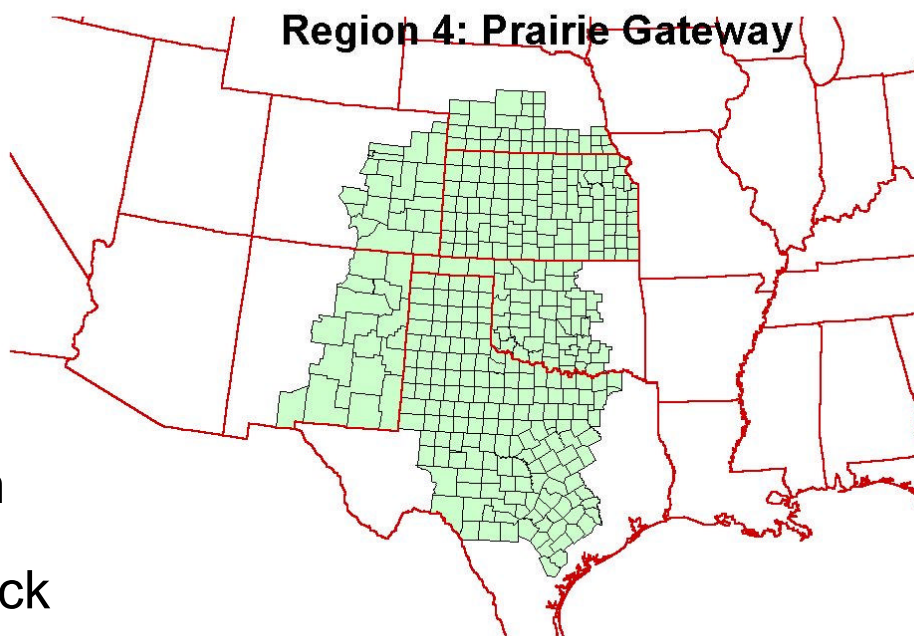


YSNG, BS(HED, CEB)



## Region 4 – *Prairie Gateway*

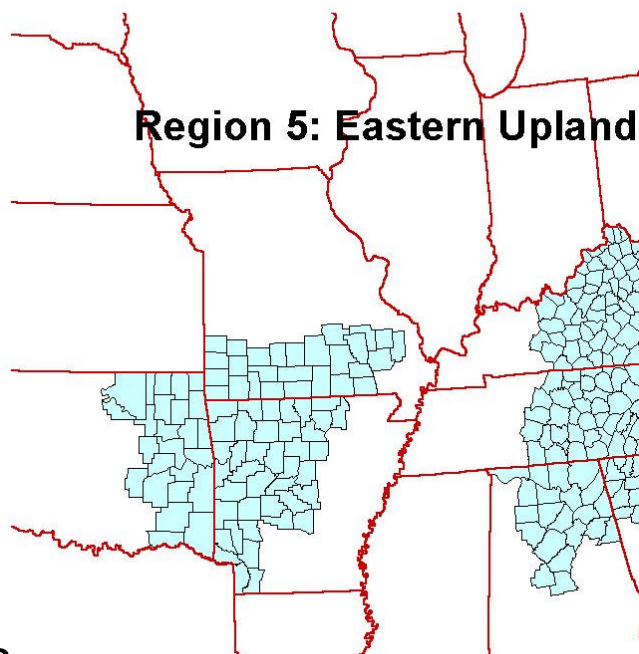
- Lawn - Bensulide, DDVP, Malathion, Trichlorfon
- Golf course - Acephate, Bensulide, Fenamiphos, Malathion, Trichlorfon
- Ornamental gardens - Acephate, Disulfoton, Malathion
- Home gardens - Malathion
- Indoor (pest strips and crack and crevice treatments)
- Public Health - Malathion





## Region 5 – *Eastern Uplands*

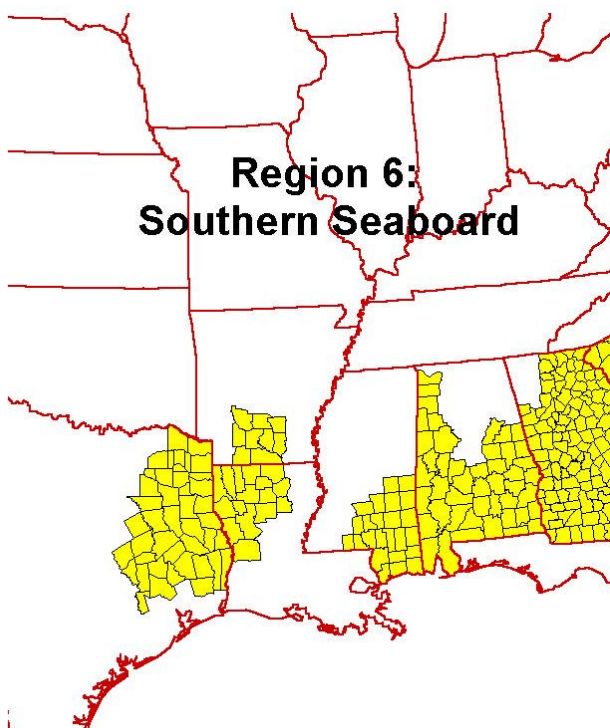
- Lawn - DDVP, Malathion, Trichlorfon
- Golf course - Acephate, Bensulide, Fenamiphos, Malathion, Trichlorfon
- Ornamental gardens - Acephate, Disulfoton, Malathion
- Home garden - Malathion
- Indoor - DDVP (pest strips and crack and crevice treatments)





## *Region 6 – Southern Seaboard*

- Lawn - Bensulide, DDVP, Malathion, Trichlorfon
- Golf course - Acephate, Bensulide, Fenamiphos, Malathion, Trichlorfon
- Ornamental gardens - Acephate, Disulfoton, Malathion
- Home gardens - Malathion
- Indoor - DDVP (pest strips and crack and crevice treatments)
- Public health - Malathion

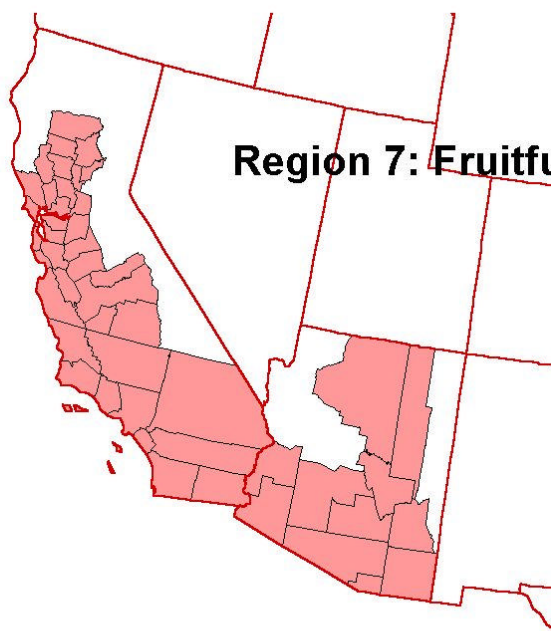




# *Region 7a,b – Fruitful Rim, CA*

(North Central and South Central Valley)

- Lawn - DDVP, Malathion, Trichlorfon
- Golf course - Bensulide, Fenamiphos, Trichlorfon
- Ornamental gardens - Acephate, Disulfoton, Malathion
- Home gardens - Malathion
- Indoor - DDVP (pest strips and crack and crevice treatments)





## Region 8 – Basin & Range

- Lawn - DDVP, Malathion, Trichlorfon
- Golf Course - Bensulide, Trichlorfon
- Ornamental Gardens - Acephate, Disulfoton, Malathion
- Home gardens - Malathion
- Indoor - DDVP (pest strips and crack and crevice)

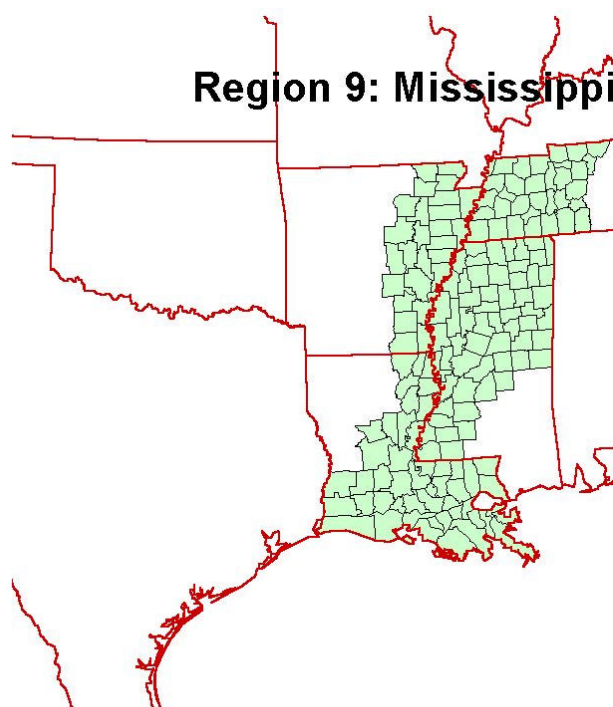
**Region 8: Basin and Range**





## *Region 9 – Mississippi Portal*

- Lawn - DDVP, Malathion, Trichlorfon
- Golf course - Acephate, Trichlorfon
- Ornamental gardens - Acephate, Disulfoton, Malathion
- Home gardens - Malathion
- Indoor - DDVP (pest strips and crack and crevice)
- Public health - Malathion, Fenthion

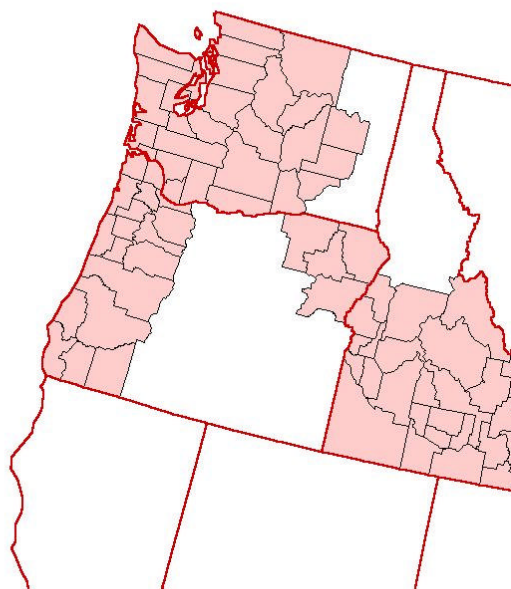




## *Region 10 – Fruitful Rim, NW*

- Lawn, DDVP, Malathion, Trichlorfon
- Golf course - none
- Ornamental gardens - Acephate, Disulfoton, Malathion
- Home gardens - Malathion
- Indoor - DDVP (pest strips and crack and crevice)

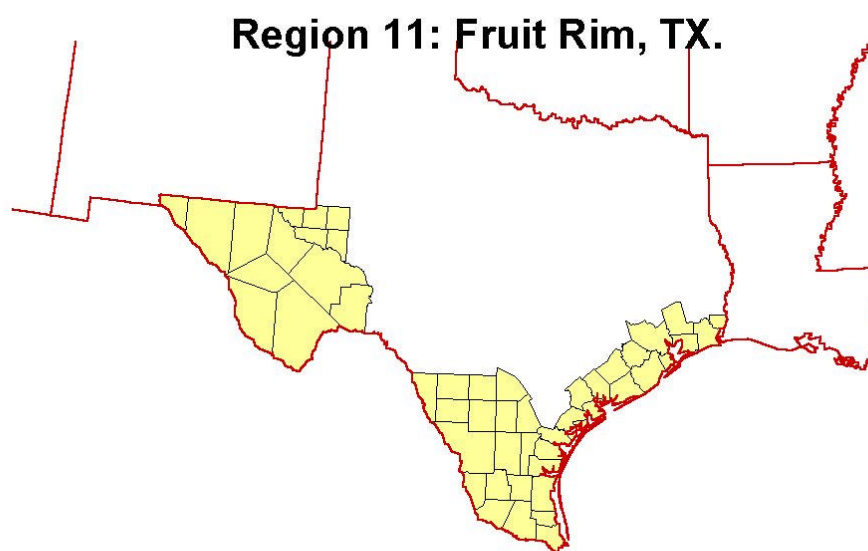
**Region 10: Fruit Rim, N**





## *Region 11 – Fruitful Rim, TX*

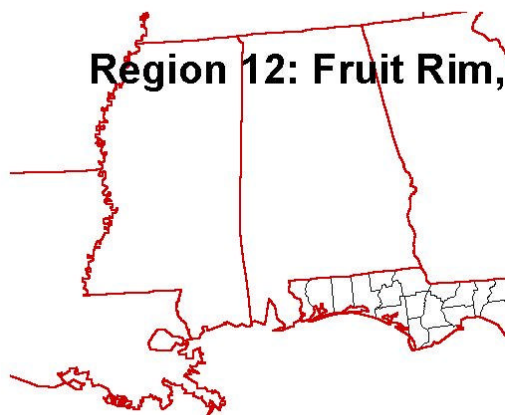
- Lawn - Bensulide, DDVP, Malathion, Trichlorfon
- Golf courses - Acephate, Bensulide, Fenamiphos, Malathion, Trichlorfon
- Ornamental gardens - Acephate, Disulfoton, Malathion
- Home gardens - Malathion
- Indoor - DDVP (pest strips and crack and crevice)
- Public health - Malathion





## *Region 12 – Fruitful Rim, FL*

- Lawn - DDVP, Malathion, Trichlorfon
- Golf courses - Acephate, Bensulide, Fenamiphos, Malathion
- Ornamental gardens - Acephate, Disulfoton, Malathion
- Home gardens - Malathion
- Indoor - DDVP (pest strips and crack and crevice)
- Public health - Fenthion, Malathion, Naled





# *scope/Registrations*

- Lawn and Golf Course use
  - Lawn
    - Bensulide, dichlorvos, malathion, trichlorfon
  - Golf Course
    - Acephate, bensulide, fenamiphos, malathion, trichlorfon
- Home Garden
  - Acephate, disulfoton, malathion



# *Scope/Registrations*

- Indoor Crack and Crevice
  - Dichlorvos
- Pest Strips
  - Dichlorvos
- Public Health
  - Individual assessments include concern
  - Naled, malathion, fenthion



## *Scope/Routes - Lawns*

- Trichlorfon, dichlorvos, malathion, bensulide (Texas only)
- Self applied, treatments made by adults
  - Exposure routes (Dermal and Inhalation)
- Post application exposure following hand and professionally applied treatments
  - Exposure routes - Adults (Dermal)
  - Exposure routes - Children (Dermal and Oral)



## *Scope/Routes – Golf Course*

- Acephate, trichlorfon, bensulide, fenamiphos, malathion
- Post application exposure following professionally applied treatments
  - Exposure Routes - Adults (Dermal)



## *Scope/Routes - Garden*

- Garden
  - Shrubs, roses, flowers
  - Acephate, disulfoton, malathion
  - Applicator exposure (dermal, inhalation)
- Home crops
  - Malathion
  - Applicator exposure (dermal, inhalation)
  - Post application (dermal)



## *Scope/Routes - Indoor*

- Crack and crevice
  - Application and post application (inhalation)
- Pest strips
  - Post application (inhalation)
- Dichlorvos - very volatile



# *cope - Public Health*

- Wide area treatments (public health uses)
- Mosquitoes
  - Northern Crescent, Southern Seaboard, Mississippi Portal, Fruitful Rim (FL)
- Black Fly
  - Northern Crescent
- Post application
  - Dermal adults, children
  - Oral, children



## *Lawns – Use Information*

- National Home & Garden Pesticide Use Survey (NHGPUS 1991)
- Doane - *Golftrak* 1997, 1998
- Treated lawns based on regions using the *National Garden Survey* 1996-1997
  - Includes:
    - Percent of population participating in lawn care activities
    - Percent of population using insecticides
- Lawn Size (Vinlove and Torla 1995 and ORETF Survey)



## *awns – Use Information*

- Chemical-specific turf residue data
- Certified/Commercial Pesticide Applicators
- State Cooperative Extension services
- Comparative Insecticide Effectiveness for Major Pest Insects of Turf in the United States



# *awn – Applicator Exposure Data*

- Data source: ORETF
- Application type:
  - Granular push-type rotary spreaders
  - Hose-end sprayer – ready to use and one requiring the user to add the concentrate
- Clothing types:
  - Range of clothing
  - Short-sleeved shirt, short pants and long-sleeved shirt, long pants



## Lawn – *Post Application Exposure Data*

- Residue transfer to skin (transfer coefficient)
  - Choreographed Activities of Adults Measured Using Biological Monitoring *Vacarro 1996*
  - Non-Scripted Activities of Children Measured Using Fluorescent Tracers *Black 1993*
- Chemical-specific lawn residue data



## Lawn – Post Application Exposure Data

- Non-Dietary Ingestion (Hand-to-Mouth)
  - Hand-to-mouth frequency of events *Reed 1999*
  - Lawn residue data to account for saliva wetted hands *Clothier 2000*
  - Saliva extraction e.g., *Camann 1995*



## *Golf Courses – Post Application Exposure Data*

- Percent of individuals participating in golf, 1992 Golf Course Operations by the Center for Golf Course Management
- Percent of Golf Courses Applying Selected Pesticides - Doane GolfTrak, 1998-1999.
- Residue transfer to skin (transfer coefficient)
  - Post application
  - Dermal route
- Chemical-specific turf residue data



# *Public Health – Post Application*

- Spray drift model
- Range of Deposition from applications based on use of AgDrift (as discussed in REDs)
- Deposition on lawns and post application is assessed in the same way lawn chemicals are
- Timing and pesticide used based on personal communication and publications prepared by organizations such as the Florida Coordinating Council of Mosquito Control



## *Garden – Applicator Exposure Data*

- Application of shaker can, garden duster, and small tank sprayer using proprietary data
- Applicator exposure dermal and inhalation
- Post application dermal exposure
  - Range of transfer coefficients from ARTF
- Duration of garden activities ORETF Survey



# *Indoor – Inhalation Exposure Data*

- Dichlorvos - range of inhalation exposure values for pressurized aerosol can (PHED)
- Post application inhalation exposure (adults and children)
- Pest strips
  - Collins et al., 1973
- Crack and crevice
  - Gold et al., 1983
- Duration of time spent indoors
  - Exposure Factors Handbook



## *n Summary*

- All available data considered
- Lawns
  - Lawn residue data available for all compounds
  - Regional adjustments where feasible
- Home gardens DFR data from ARTF studies
  - CA and PA
- Wide Area treatments
  - Transfer efficiency based on chemical specific lawn residue data (except fenthion - assumed to be similar to malathion based on similar molecular weights and vapor pressure)





# Summary & Next Steps

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Director

Special Review &  
Reregistration Division



# oadmap



Probabilistic methods for cumulative



Proposed method for food



Residential uses



Proposed methods for residential



**Summary & next steps**



# *Summary of Cumulative Food & Residential Assessment Methods*

- Food assessment:
  - Probabilistic assessment
  - Uses best available monitoring data
- Residential assessment:
  - Probabilistic assessment done with daily distribution of estimated residues
  - Regional assessment in order to combine residential (& water) on a realistic, localized scale
  - Focuses on realistic co-occurrences



## *Next Steps*

- All data considered for the food & residential exposure assessment will be available with the preliminary assessment



# *Next Steps*

## **November 2001**

- Release various revised science policy papers

## **December 2001**

- Release preliminary risk assessment

## **January 15, 2002**

- Technical briefing on preliminary cumulative risk assessment

## **January 16, 2002**

- CARAT Workgroup meets

## **Winter 2002 (Feb. 5-8 scheduled)**

- SAP Meeting on preliminary risk assessment

## **Winter 2002 (likely through March 8th)**

- Comment period on preliminary risk assessment

## **August 2002**

- Release revised risk assessment



## *Next Steps*

For the most up-to-date information, visit:

- <http://www.epa.gov/pesticides/cumulative/>

To receive OPP Updates via e-mail:

- See the sign-up sheet at the registration desk